UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,922	08/31/2001	Vassilios Papadopoulos	1941.017US1	9599

21186 7590 09/30/2008

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
DANG, IAN D	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
09/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/623,922	PAPADOPOULOS ET AL.	
	Examiner	Art Unit	
	IAN DANG	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-9,20-26,29,30,32 and 39* is/are pending in the application.

4a) Of the above claim(s) *9,20-26,29,30,32 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/30/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

At page 6 of the response, Applicants argue that the elected invention (see the Response to Restriction Requirement mailed on July 31, 2006) is directed to a cholesterol recognition/interaction amino acid consensus sequence comprising $Z-(X)_{0-5}-Y-(X)_{0-5}-Q$ (SEQ ID NO:26), wherein Z is a neutral hydrophobic amino acid, Y is a neutral polar amino acid, Q is a basic amino acid and X is any amino acid, and that claim 39 is directed to a peptide having a cholesterol recognition/interaction amino acid consensus sequence, wherein the peptide consists of $(X)_{0-4}-Z-(X)_{0-5}-Tyr-(X)_{0-5}-B-(X)_{0-5}$ (SEQ ID NO:27) wherein Z is leucine or valine (neutral hydrophobic amino acids), B is arginine or lysine (basic amino acids) and X is any amino acid. Therefore, claim 39 is directed to the elected invention.

Applicants' arguments have been considered have been considered but are not found persuasive. Although the elected invention is drawn to a peptide having a cholesterol recognition/interaction amino acid consensus sequence, the peptide consisting of $Z-(X)_{0-5}-Y-(X)_{0-5}-Q$ (SEQ ID NO:26) is patentably distinct from the peptide consisting of $(X)_{0-4}-Z-(X)_{0-5}-Tyr-(X)_{0-5}-B-(X)_{0-5}$ (SEQ ID NO:27). The peptides have different structures from one another because they are made up of different amino acid residues and have different length. In addition, these 2 peptides are of different scope, since the amino acid sequence for SEQ ID NO:26 has a different length from the amino acid sequence of SEQ ID NO:27. Therefore, the amino acid of SEQ ID NO:27 recited in claim 39 is patentably distinct from the elected invention of SEQ ID NO:26 and has been withdrawn from further consideration.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9, 21-26, 29,32, and 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Status of Application, Amendments and/or Claims

The amendment of 30 June 2008 has been entered in full. Claims 3, 10-19, 27, 28, 31, 33-38 have been cancelled.

Claims 1, 2, 4-8, and 20 are under examination.

Claim Rejections - 35 USC § 112 (Written Description)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-8 and 20 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

At page 6 of the response, Applicants argue that the claims and specification clearly indicate conserved regions, i.e., the tyrosine residue, the neutral hydrophobic amino acid Z and the basic amino acid B in Z-$(X)_{0-5}$-Tyr-$(X)_{0-5}$-B. Moreover, the sites at which variability may be

tolerated are also clearly indicated, i.e., $(X)_{0-5}$ wherein X is any amino acid. And with respect to structural characteristics associated function, claim 1 recites that in Z-$(X)_{0-5}$-Tyr-$(X)_{0-5}$-B (structure) is a cholesterol recognition/interaction (function) amino acid consensus sequence.

Applicants' arguments have been considered but are not found persuasive. Applicants have not satisfied the requirements for written description because the specification and claim does not provide sufficient structural characteristics, which are definitive of all "cholesterol recognition/interaction amino acid consensus sequence" with the desired activity. Although the specification discloses the functional property as a cholesterol recognition amino consensus sequence, which is common to the "consensus sequence", it does not identify those defining structural elements which provide the structural properties of all such consensus sequences. For instance, claim 1 recites that Z is any neutral hydrophobic amino acid, B is a basic amino acid, and X is any amino acid. Although claim 1 recites 3 amino acid residues (Z, Tyr, and B) in the consensus sequence, there are 10 amino acid residues in the sequence that can be any amino acid residues. Therefore, the recitation of claim 1 for the claimed consensus sequence provides structural information to only 3 out 13 amino acid residues of the consensus sequence or 23% of the sequence. The recitation of claim 1 does not provide sufficient specific structural characteristics for the amino acid residues X of the consensus sequence that can be used to identify the cholesterol recognition/interaction amino acid consensus sequence. The specification does not disclose the structural characteristics of the amino residues X and the number of amino acid residues X that would be needed to retain the function as a cholesterol recognition/interaction amino acid consensus sequence.

Based on Applicants' disclosure and knowledge within the art, those of skill in the art would conclude that Applicants would not have been in possession of the claimed genus of the consensus sequence Z-$(X)_{0-5}$-Tyr-$(X)_{0-5}$-B based on the disclosure of the species of cholesterol

recognition/interaction amino acid consensus sequence comprising VLNYYNWR (SEQ ID NO:5) of peripheral-type benzodiazepine receptor (PBR) and relevant identifying characteristics. Thus, applicant was not in possession of the claimed genus and the written description requirement is not satisfied.

Claim Rejections - 35 USC § 112 (Enablement)

Claims 1, 2, 4-8, and 20 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At page 7 of the response, Applicants argue that it is well within the skill of the art to prepare recombinant peptides or polypeptides having the consensus sequence. Moreover, if a manner of using a claimed invention is available to one of ordinary skill in the art, the "how to use" requirement of 35 U.S.C. § 112(1), has been satisfied. In re Nelson, 126 U.S.P.Q. 242 (C.C.P.A. 1960).

In addition, Applicants allege that the Examiner has not provided objective evidence to doubt the assertion that the cholesterol recognition/interaction amino acid consensus sequence, either alone or in the context of other sequences so as to form a mutant polypeptide or a fusion polypeptide, is capable of interacting or recognizing cholesterol. In this regard, the Examiner is requested to consider Li et al. (.Proc. Natl. Acad. Sci. USA, 9 88:1267 (2001)) (a copy is enclosed herewith) which disclose the inhibition of steroidogenesis by an HIV TAT-cholesterol recognition/interaction amino acid consensus peptide, and Wang et al. (J. Biol. Chem.,

283:8034 (2008)) (a copy is enclosed herewith) which disclose that a sterol binding domain of OSBP is functional whether attached to the N- or the C-terminal half of OSBP.

Applicants' arguments and response have been considered but are not found persuasive. Although the Examiner agrees with Applicants that it is within the skill of the art to prepare recombinant peptides, one of skill in the art would require undue experimentation to include the consensus sequence in a polypeptide because the specification and claims do not provide sufficient specific structural characteristics for the cholesterol recognition amino acid consensus sequence.

A large amount of experimentation would be required to be able to practice the invention commensurate in scope with the claims because the claims and specification do not provide any identifying structural and functional characteristics associated with a biological activity for an isolated cholesterol recognition/interaction amino acid consensus sequence. Applicant has also provided little or no guidance beyond the mere presentation of sequence data to enable the skilled artisan to determine, without undue experimentation, the positions in the cholesterol recognition/interaction amino acid consensus consisting of SEQ ID NO:26 which are tolerant to change (e.g. such as by amino acid substitutions, additions or deletions) and the nature and extent of changes that can be made in these positions.

In addition, the examiner has provided an objective analysis of the facts disclosed on the specification for the claimed isolated cholesterol recognition/interaction amino acid consensus sequence. The recitation of claim 1 for the isolated cholesterol recognition/interaction amino acid consensus sequence wit the structural formula $Z\text{-}(X)_{0\text{-}5}\text{-Tyr-}(X)_{0\text{-}5}\text{-B}$ does meet the enablement requirement because Applicants have not provided sufficient structural identifying characteristics for the claimed consensus. For instance, claim 1 recites that Z is any neutral hydrophobic amino acid, B is a basic amino acid, and X is any amino acid. Therefore, the

structural formula Z-$(X)_{0-5}$-Tyr-$(X)_{0-5}$-B represents a large number of sequences of different length with many different amino acid residues. Although claim 1 recites 3 amino acid residues (Z, Tyr, and B) in the consensus sequence, there are 10 amino acid residues in the sequence that can be any amino acid residues. Therefore, the recitation of claim 1 for the claimed consensus sequence provides structural information to only 3 out 13 amino acid residues of the consensus sequence or 23% of the sequence. The specification does not disclose the structural characteristics of the amino residues X and the number of amino acid residues X that would be needed to retain the function as a "cholesterol recognition/interaction amino acid consensus sequence.

After reviewing the reference by Li et al., the examiner has been able to find the cholesterol recognition sequence CRAC: ATVLNYYVWRDNS (page 1267, abstract). However, the examiner has not been able to find a consensus sequence for the sterol binding domain of OSBP. Although the reference by Li et al. provides one example for a specific sequence for an isolated cholesterol recognition/interaction amino acid consensus sequence, this particular sequence is not sufficient to meet the enablement requirement for the claimed invention for the claimed consensus sequence Z-$(X)_{0-5}$-Tyr-$(X)_{0-5}$-B based on the disclosure of CRAC: ATVLNYYVWRDNS.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
September 24, 2008

/Robert Landsman/
Primary Examiner, Art Unit 1647